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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,636	YU, SU-MAY	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *1-16,21 and 36-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-19,22,24-28 and 34* is/are rejected.

7)☒ Claim(s) *20,23,29-33 and 35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/3/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence search result*.

5.00.

DETAILED ACTION

1. Claims 1-41 are pending.

2. Applicant's election without traverse of Group II, claims 17-20 and 22-35, to the extent that they are drawn to SEQ ID NO:1 encoding SEQ ID NO:7 in the reply filed on 7/14/2005 is acknowledged.

Claims 1-16, 21, and 36-41 are withdrawn from consideration for being drawn to non-elected inventions.

3. Claims 17-20 and 22-35 are examined in the present office action.

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See for example page 4, line 21. See MPEP § 608.01.

Claim Objection

5. Claims 17-20 and 22-35 are objected to for being drawn to non-elected inventions. The rejection includes dependent claims. Correction is requested.

Claims 19-20, 23, 29-33 and 35 are objected to for being dependent on a non-elected claim. For purposes of compact prosecution, the claims will be examined including the limitations of the non-elected claims. Correction is requested.

Claims 20, 23, and 29-33 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on a multiple dependent claim. See MPEP § 608.01(n). Correction is requested.

Claim 19 is objected to for reciting "a polypeptide" instead of --the polypeptide--.

Claims 23, is objected to for reciting "a nucleic acid" instead of --the nucleic acid--.

Claims 24, line 1, is objected to for reciting "a nucleic acid" instead of --the nucleic acid--.

Claims 29, is objected to for reciting "a nucleic acid" instead of --the nucleic acid--.

Claim 35 is objected to for reciting "a polypeptide" instead of --the polypeptide--.

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 17-19, 22, 24-28 and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated nucleic acid that hybridizes under stringent conditions to SEQ ID NO:1, or a complement sequence thereof, or a complement of SEQ ID NO:1, or wherein the nucleic acid encodes a polypeptide that is 70% identical to SEQ ID NO:7;

a cell comprising said sequence, or a transgenic plant comprising said sequence; or a method of expressing a transcript in a cell comprising introducing a vector into a cell wherein the vector comprises a nucleic acid that hybridizes under stringent conditions to SEQ ID NO:1 or a complementary sequence thereof.

Applicant isolated the invention from a suspension cell culture of rice (Oryza sativa cv. Tainan 5) (page 10, line 1). A cDNA sequence was isolated from a cDNA library made from said cells, using nucleotides -133 to -82 of the αAmy3 promoter (the sugar response sequence, SRS, of the amylase gene) as a probe, in a South-Western screen. The resultant cDNA sequence of SEQ ID NO:1 encodes the OsMYBS1 protein of SEQ ID NO:7 (page 11, Number 3; page 3, lines 12-16). A genomic library was screened using a 613 bp DNA fragment containing the 220 bp coding region and the 393 bp 3' untranslated region of the OsMYBS1 cDNA (page 11-12, number 5). Applicant discloses that a total of three OsMYBS proteins were isolated in the screen and that they are most closely related to MybSt1 (StMYB1), and that StMYB1 transactivates the cauliflower mosaic virus 35SRNA gene promoter (page 16, lines 1-12). Applicant discloses that the three OsMYBS's contain a 1R sequence (in their DNA binding domains); 1R from OsMYBS1 compared to 1R from OsMYBS3 =87% identical and 1R from OsMYBS1 compared to 1R from OsMYBS2 = 77% identical (page 16, lines 18-14). Applicant also discloses that there is very low homology among the N- and C- terminal regions outside the 1R regions of all the MYB proteins (page 16, lines 22-25).

The Applicants do not identify essential regions specific to OsMYBS1 protein encoded by SEQ ID NO:1 other than the 1R region, nor do Applicants describe any polynucleotide sequences that hybridize under stringent conditions to SEQ ID NO:1 and/or which encode a

protein exhibiting at least 70% identity to SEQ ID NO:7 and that encodes a functional OsMYBS1 protein.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding an OsMYBS1 protein falling within the scope of the claimed genus of polynucleotides which hybridize to SEQ ID NO:1 and/or which encode a protein exhibiting at least 70% identity to SEQ ID NO:7. Applicants only describe a single cDNA sequence of SEQ ID NO:1. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the OsMYBS1 protein, it remains unclear what features identify a rice OsMYBS1 protein.

Since the genus of OsMYBS1 proteins has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Scope of Enablement

7. Claims 17-19, 22, 24-28 and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:1 encoding SEQ ID NO:7 wherein SEQ ID NO:7 binds to a sugar response sequence (SRS) and effects transcription of a coding sequence operably linked to the SRS, does not reasonably provide enablement for nucleic acid sequences that hybridize to SEQ ID NO:1 or a complement of SEQ ID NO:1 and encode a protein or nucleic acid sequences that encode a protein exhibiting at least 70% identity to SEQ ID NO:7; and plant or plant cell transformation therewith. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to an isolated nucleic acid that hybridizes under stringent conditions to SEQ ID NO:1, or a complement sequence thereof, or a complement of SEQ ID NO:1, or wherein the nucleic acid encodes a polypeptide that is 70% identical to SEQ ID NO:7; a cell comprising said sequence, or a transgenic plant comprising said sequence; or a method of expressing a transcript in a cell comprising introducing a vector into a cell wherein the vector comprises a nucleic acid that hybridizes under stringent conditions to SEQ ID NO:1 or a complementary sequence thereof.

The Office interprets "a complementary sequence thereof" to read on a large number of sequences because "a complementary sequence thereof" reads on as little as one base pair.

Applicant isolated the invention from a suspension cell culture of rice (Oryza sativa cv. Tainan 5) (page 10, line 1). A cDNA sequence was isolated from a cDNA library made from said cells, using nucleotides -133 to -82 of the αAmy3 promoter (the sugar response sequence, SRS, of the amylase gene) as a probe, in a South-Western screen. The resultant cDNA sequence of SEQ ID NO:1 encodes the OsMYBS1 protein of SEQ ID NO:7 (page 11, Number 3; page 3, lines 12-16). A genomic library was screened using a 613 bp DNA fragment containing the 220 bp coding region and the 393 bp 3' untranslated region of the OsMYBS1 cDNA (page 11-12, number 5). Applicant discloses that a total of three OsMYBS proteins were isolated in the screen and that they are most closely related to MybSt1 (StMYB1), and that StMYB1 transactivates the cauliflower mosaic virus 35SRNA gene promoter (page 16, lines 1-12). Applicant discloses that the three OsMYBS's contain a 1R sequence (in their DNA binding domains); 1R from OsMYBS1 compared to 1R from OsMYBS3 =87% identical and 1R from OsMYBS1 compared to 1R from OsMYBS2 = 77% identical (page 16, lines 18-14). Applicant

also discloses that there is very low homology among the N- and C- terminal regions outside the 1R regions of all the MYB proteins (page 16, lines 22-25). Applicant discloses that the function of the three OsMYBS's is different by stating "This result indicates that OsMYBS1 activates, while OsMYBS2 and OsMYBS3 repress, transcription of a promoter containing only the TATCCA element and adjacent flanking sequences" (page 21, lines 14-16).

The state-of-the-art teaches that not all proteins that have transactivation capabilities produce expected results. Schwechheimer et al (2000, Funct Intergr Genomics 1:35-43) teach self-amplifying transactivation systems have inherent problems which leads to unpredictability within the system. They report "Many genes encoding transcriptional activators are differentially expressed or activated in different tissues at different stages of organismal development or in response to environmental stimuli" (page 35, right column, 1st paragraph). In addition, "numerous transcriptional activators vary in their strength and possibly in some cases also in their tissue-specific activity" (page 41, left column, 2nd paragraph). They also report that target gene silencing is a problem that can occur if there is a high concentration of transcription factors within the nucleus (page 41, right column, 1st paragraph) or that the upstream activation sequences become methylated. Schwechheimer et al state "It has been postulated that the GAL4-promoter binding sites may be methylated and that methylation interferes with promoter activity" (page 41, right column, 1st paragraph). Schwechheimer et al also teach that not all promoters confer the same level of expression in all plant system (page 36, left column, 2nd paragraph).

Applicant's claims are drawn to nucleic acid sequences that hybridize under stringent conditions to SEQ ID NO:1, but the state-of-the-art teaches isolating DNA fragments using

stringent hybridization conditions, does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe. Fourgoux-Nicol et al (1999, Plant Molecular Biology 40 :857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65^0C (page 859, left column, 2^{nd} paragraph). Fourgoux-Nicol et al also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2).

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that hybridize under stringent conditions to SEQ ID NO:1 or nucleic acids that encode a protein exhibiting 70% identity to SEQ ID NO:7 will encode a protein with the same activity as a protein encoded by SEQ ID NO:1. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex, and the positions within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of maintaining function are limited (Bowie et al, Science 247:1306-1310, 1990, see especially page 1306). Proteins may be sensitive to alterations in even a single amino acid in a sequence. For example, the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the

sterol/lipid binding domain (McConnell et al, Nature 411 (6838):709-713, 2001, see especially page 710, left column, 2nd paragraph).

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:1 as probes or by designing primers to undisclosed regions of SEQ ID NO:7 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed produce a OsMYBS1 protein that can bind to a SRS sequence and activate transcription of a gene operably linked to the SRS sequence.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 17 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Dong et al (November 2001, NCBI Accession Number BM038003).

The claims are drawn to an isolated nucleic acid that hybridizes under stringent conditions to SEQ ID NO:1 or a complementary sequence thereof or a complementary sequence of SEQ ID NO:1.

The Office interprets "a complementary sequence thereof" to read on a large number of sequences because "a complementary sequence thereof" reads on as little as one base pair.

Dong et al disclose a nucleic acid sequence that exhibits 92% identity to nucleotides 993 to 1324 of SEQ ID NO:1 and which would hybridize under stringent conditions thereto, and given the interpretation of "a complementary sequence thereof" as discussed above, Dong et al anticipates the claimed invention.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 17-18, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Klessig et al et al (August, 1999, U.S. Patent Number 5,939,601).

The claims are drawn to an isolated nucleic acid that hybridizes under stringent conditions to SEQ ID NO:1 or a complementary sequence thereof or a complementary sequence of SEQ ID NO:1, or a cell or transgenic plant expressing said nucleic acid.

The Office interprets "a complementary sequence thereof" to read on a large number of sequences because "a complementary sequence thereof" reads on as little as one base pair.

Klessig et al disclose a nucleic acid sequence encoding a myb protein and a plant transformed therewith (columns 33-34, claims 1-18). Given the interpretation of "a

complementary sequence thereof" as discussed above, Klessig et al anticipates the claimed invention.

10. No claims are allowed.

Claims 20, 23, 29-33 and 35 are objected to.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
September 6, 2005